EXHIBIT P

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December 1, 2017

VIA E-MAIL AND FEDEX

The Honorable Eric D. Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: Eric.Hargan@hhs.gov

Re: Tamiany de La Rosa / OPTN Liver Allocation Policy

Dear Secretary Hargan:

This firm represents Tamiany de La Rosa, a 25-year-old woman who is currently at Mount Sinai Medical Center in New York awaiting a liver transplant. The issues raised in this letter are of utmost urgency and are literally a matter of life and death. We request that you give this letter your immediate attention so that you can either grant our request or we can seek immediate emergency judicial relief.

Request

We request that you take immediate action and direct the Organ Procurement and Transportation Network (OPTN) to set aside those portions of OPTN Policy 9 that require livers from deceased donors to be allocated to candidates based on arbitrary geographical boundaries instead of medical priority. Specifically, we request that you direct the OPTN to revise the allocation of livers provided for in Table 9-6 to be based on

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medical criteria instead of arbitrary geographic limitations such as the Organ Procurement Organization's (OPO) region or OPO's donor service area (DSA).

Under longstanding OPTN policy, organs are to be prioritized among potential candidates by medical priority. With regard to livers, medical priority is largely determined by a candidate's Model for End-Stage Liver Disease (MELD) score, which is a priority ranking of 6 to 40. Ms. de La Rosa has a MELD score of 40 putting her at the top of the list for a liver transplant.

The OPTN has 58 Organ Procurement Organizations, or OPOs, throughout the United States, each of which serves within the bounds of its DSA. OPTN's current policy provides that when a liver becomes available it is first made available to candidates within the local DSA even if there are candidates with a higher medical priority, *i.e.*, a higher MELD score, within range of the liver or even closer. By prioritizing livers to the local OPO region or DSA, OPTN limits the number of livers available to high priority transplant candidates like Ms. de La Rosa and effectively allocates available livers based on a candidate's place of residence instead of medical priority. This policy is in direct contravention of the OPTN's legislative mandate which requires allocation based on medical priority.

By way of example, Ms. de La Rosa has a MELD score of 40, which indicates an extremely high level of medical need for a transplant and puts her in the top 0.5% of patients awaiting livers based on that measure. Ms. de La Rosa is registered as a candidate at Mount Sinai Medical Center, which is located in the DSA for southeastern New York. That DSA is serviced by LiveOnNY, the DSA's OPO. If a liver suitable for Ms. de La Rosa became available from a donor in Newark, New Jersey (just a few miles from Ms. de La Rosa), the liver would be offered first to all suitable candidates in the DSA encompassing Northern and Central New Jersey, regardless of whether those candidates' MELD scores were higher or lower than Ms. de La Rosa's. Moreover, that candidate would likely be *geographically further away* from the donated liver than Ms. de La Rosa.

Ms. de La Rosa is not looking for any special treatment. She is only asking that you exercise your authority to set aside an antiquated and inflexible policy established by a federally-created organization supervised by your Department, so that Ms. de La Rosa can be considered for available livers based on her medical priority without regard for arbitrary geographical boundaries.

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After Nearly Two Decades, It is Time to Change OPTN Liver Policy

The OPTN has long recognized that its liver allocation policy is inequitable as a result of arbitrary geographic boundaries. It has been nearly twenty years since the implementation of the Final Rule, which mandates allocation policies be based on sound medical judgment – and not based on the candidate's place of residence or place of listing. Over the last two decades much discussion has been had and many studies have been conducted but the OPTN has still been unable to implement a system for livers that complies with the legislative mandate that organ allocation be based on medical – not geographic – priority. The OPTN has had nearly twenty years to study and fix the liver allocation system. It is now time for the Secretary to exercise his authority and take charge.

Authority

The Secretary has the authority to direct United Network for Organ Sharing (UNOS) and OPTN to take action under 42 C.F.R. 121.4(d)(2) and (3). Those provisions provide the Secretary with authority to "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments" or "[t]ake such other action as the Secretary determines appropriate." The Secretary also has authority to vary OPTN policies on a limited basis under 42 C.F.R. 121.8(g).

Background

1. Tamiany de La Rosa

Tamiany de La Rosa is a 25-year-old woman with methylmalonic acidemia, a disease that prevents the body from processing certain proteins and fats. Ms. de La Rosa particular condition is quite severe and without a liver transplant will likely die in the near term

Ms. de La Rosa has been admitted at Mount Sinai Hospital in New York since October 16, 2017, and was listed as a liver transplant candidate on July 21, 2017. She is waitlisted for a liver at Mount Sinai, which is in the OPO for southeastern New York and DSA Region 9. As stated above, Ms. de La Rosa has a MELD score of 40, which puts her in the top 0.5% of patients awaiting a liver based on the urgency of her medical need.

2. OPTN and UNOS

The National Organ Transplant Act of 1984 (NOTA) created the OPTN. The current version of NOTA is codified at 42 U.S.C. § 274, which provides that the

Secretary must establish and operate the OPTN in accordance with the requirements of NOTA.

NOTA empowers the Secretary of the Department of Health and Human Services (HHS) to contract with UNOS, a non-profit private organization, to operate the OPTN. The Secretary contracts with UNOS through the Health Resources and Services Administration (HRSA). The Secretary has also promulgated regulations that govern the OPTN (42 C.F.R § 121). These regulations provide, among other things, that OPTN's Board of Directors shall be responsible for developing policies for the operation of the OPTN, including "[p]olicies for the equitable allocation of cadaveric organs in accordance with §121.8." 42 C.F.R. §121.4(a)(1).

Section 121.8(a) provides as follows:

(a) ***Policy development.*** The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

> **(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.**

42 C.F.R. §121.8(a) (emphasis added).

NOTA and regulations promulgated thereunder clearly require that OPTN policies for organ allocation be equitable, that they provide for organ allocation based on medical severity, and that they *not* base organ allocation on a candidate's place of residence or listing. Ms. de La Rosa does not seek special treatment. She only asks for the equitable treatment that she is entitled to under the law, based on the sound medical judgment of her doctors.

3. OPTN's Liver Allocation Policy Unfairly Allocates Livers Based on Geography

The OPTN rules for allocation of livers are set forth in OPTN Policy 9.

Policy 9.6.E. (Allocation of Livers from Deceased Donors at Least 18 Years Old) provides that "[l]ivers from deceased donors at least 18 years old are allocated to candidates according to *Table 9-6* below." Table 9.6 (Allocation of Livers from Deceased Donors at Least 18 Years Old) sets forth 52 classifications of allocation priority. Unlike other organs that allocate among candidates based on medical priority and non-arbitrary geographic limitations, the liver allocation system includes arbitrary geographic limitations based on OPO region or OPO DSA.

Under the current system, if a liver is accepted for a candidate listed with a MELD score within the local DSA, it is never offered to a candidate in the broader reach of the organ even if that non-local DSA candidate has a greater medical need, *i.e.*, a higher MELD. Moreover, because of the arbitrary boundaries of DSAs, an available liver may not even be offered to the candidate closest to the donor hospital even if that candidate has a higher MELD score. Instead of following such a patently illogical allocation priority rule, organs should be made available to a candidate with Ms. de La Rosa's recognized level of transplant need based on a logistically reasonable radius of her transplant hospital. Although livers have a preservation of time that is 200% of hearts and lungs – up to 12 hours or longer – livers are still allocated based on arbitrary local boundaries, while other organs have transitioned to a non-arbitrary prioritization.

Simply put, OPTN Policy 9 is discriminatory and violates the legislatively mandated requirement that organ allocation be "based on sound medical judgment" and

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"not be based on the candidate's place of residence or place of listing." 42 C.F.R. §121.8(a).

4. OPTN's Policy 9 Is Recognized by OPTN and the Medical Community as Being Discriminatory

For years, the medical community has recognized the requirement that livers be allocated within the local OPO or DSA before being offered more broadly is dangerously flawed. Multiple medical studies support the need for a change to the current policies that allocate livers based on arbitrary geographical boundaries. Gentry SE, Massie AB, Cheek SW, Lentine KL, Chow EH, Wickliffe CE, Dzebashvili N, Salvalaggio PR, Schnitzler MA, Axelrod DA, Segev DL, *Addressing geographic disparities in liver transplantation through redistricting*, American Journal of Transplantation, 2013; 13:2052-2058 (Exhibit A); Yeh H, Smoot E, Shoenfeld DA, Markmann JF, *Geographic inequity in access to livers for transplantation*, Transplantation 2011; 91: 479-486 (Exhibit B); Schwartz A, Schiano T, Kim-Schluger L, Florman S, *Geographic disparity: the dilemma of lower socioeconomic status, multiple listing, and death on the liver transplant waiting list*, Clinical Transplantation 2014; 28: 1075-1079 (Exhibit C); Axelrod DA, Vagefi PA, Roberts JP, *The evolution of organ allocation for liver transplantation: tackling geographic disparity through broader sharing*, Annals of Surgery August 2015; Vol. 262, No. 2, 224-227 (Exhibit D).

Conclusion

HHS, OPTN, and Ms. de La Rosa all have a common goal – to make livers available to those who need them the most based on medical criteria. All we request is that this goal be appropriately reflected in OPTN Policy 9 and that it be done in a timely manner so that it is not too late for Ms. de La Rosa. Ms. de La Rosa is not asking for anything more than she is entitled to under NOTA. It cannot possibly be that the system is so rigid that despite the compelling facts set forth in this letter Ms. de La Rosa must die rather than get a fair chance to receive a donated liver. Discretion and power rests with the Secretary to direct the OPTN for exactly this purpose – to avoid inequality and injustice. We ask that you set aside these flaws in OPTN Policy 9 until the OPTN can devise a better system after proper notice and comment to the public. The history of the OPTN's liver policy efforts shows that without intervention by the Secretary (or the judiciary, as may be necessary) the OPTN may not be able to make the necessary changes in time for liver candidates like Ms. de La Rosa and many others.

I hope that you will exercise your discretion in this matter as requested, including by directing the OPTN to initiate an emergency review of its policy for allocating livers based on arbitrary geographical boundaries. In this regard, we bring to the Secretary's

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attention the attached proposal (Exhibit E), which we understand will be discussed by the OPTN Executive Committee on December 4, 2017. This proposal recognizes the problems with the current policy but it is important for any policy adopted by the OPTN to be based on medical priority – not arbitrary geographical boundaries.

Yours truly,

Motty Shulman

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